

## UNITED STATE DEPARTMENT OF COMMERCE Patent and Trademark Office

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 APPLICATION NO.
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EXAMINER

PENNIE & EDMONDS LLP 1667 K STREET N W WASHINGTON DC 20006 LUKTON, D

ARTUNIT PAPER NUMBER

1653

**DATE MAILED:** 

07/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

## Office Action Summary

Application No. 09/450,217

**Erdmann** 

Examiner

**David Lukton** 

Group Art Unit 1653



X Responsive to communication(s) filed on May 10, 2000	· · · · · · · · · · · · · · · · · · ·
☐ This action is <b>FINAL</b> .	
☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle35 C.D. 11; 453 O.G. 213.	
A shortened statutory period for response to this action is set to expire3month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).	
Disposition of Claim	
	pending in the applicat
Of the above, claim(s) 14-22 is/are without	frawn from consideration
☐ Claim(s)	is/are allowed.
	is/are rejected.
☐ Claim(s)	is/are objected to.
☐ Claims are subject to restriction	or election requirement.
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.	
☐ The drawing(s) filed on is/are objected to by the Examiner.	
☐ The proposed drawing correction, filed on is ☐ approved ☐disapprov	ed.
☐ The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).	
☐ All ☐Some* None of the CERTIFIED copies of the priority documents have been	
received.	
received in Application No. (Series Code/Serial Number)	
received in this national stage application from the International Bureau (PCT Rule 17.2(a)).	
*Certified copies not received:	
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachment(s)	
Notice of References Cited, PTO-892	
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	
☐ Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

Applicants' election of Group I with traverse is acknowledged.

Applicants have traversed the restriction by arguing that the product claims (14-22) should be rejoined with the method claims. However, the products of claims 14-22 are known in the art; moreover, applicants have forfeited the opportunity to have the methods rejoined with the product claims because of their election of the former. The restriction between Groups 1-3 on the one hand, and Groups 4-6 on the other hand is made final. However, the possibility of rejoining Groups 2 and 3 with Group 1 is not precluded. The restriction between Groups 1, 2 and 3 is nevertheless maintained at this time.

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The abstract is objected to on grammatical grounds. The grammatical errors should be corrected. One option is the following:

A process is disclosed for extracting glycomacropeptide from a lactic raw material, said process comprising treating a lactic raw material ...[etc.]

\*

Claims 1-13 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "removing cations from a lactic raw material". There are three issues here. First, there are three types of cations possible in this situation: (a) any protein that has

an isoelectric point above 4.5 will be a "cation", or more accurately a poly-cation; (b) hydronium ion (H<sub>3</sub>O<sup>+</sup>) is a cation, and (c) metal ions such as Ca<sup>++</sup>, Mg<sup>++</sup>, Cu<sup>++</sup> and Fe<sup>+3</sup>. Are all of these intended, or just the metal ions? Second, claim 1 implies that it is possible to remove cations without also removing anions; is this intended? Third, the implication is that if one begins a solution of unspecified pH and removes cations one at a time, one will inevitably reach a pH of 1-4.5. However, this is only possible if both of the following two conditions are met: (a) the solution is initially at a pH below 1.0, and (b) the cations in question are protons. Is this really intended?

Claim 1 refers to "a sufficient temperature". Does this simply mean that the lactic material should not be frozen, or does it have some other meaning?

Claim 2, line 4 recites "demineralized to by electrodialysis". Here, the "to" appears to be superfluous.

The clarity of claim 2 would be enhanced if the letters (in alphabetic sequence) were used to separate the Markush group members, e.g., the following:

...wherein the lactic raw material is one of:

- (a) sweet whey obtained after separation of casein coagulated with rennet;
- (b) a concentrate of sweet whey;
- (c) sweet whey which has been demineralized by electrodialysis, ion exchange, reverse osmosis, electrodeionization ...
- (d) a concentrate of proteins of substantially lactose-free sweet whey obtained by ultrafiltration...

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The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-2 are rejected under 35 U.S.C. §103 as being unpatentable over Etzel (USP 5,968,586 or Etzel (WO 99/18808).

Etzel ('586 and '808) teaches acquisition of casein macropeptide from lactic raw materials by reducing the pH to below 4, and subjecting the resulting mixture to purification on a cation exchange column (bearing carboxylate or sulfonate moieties) to obtain the casein macropeptide in purified form. The reference does not teach deionizing the crude mixture prior to ion exchange chromatography. However, one of ordinary skill would have recognized that a protein solution (aqueous) of high ionic strength will not bind appreciably to an ion exchange column, and so, in an effort to obtain optimal binding of the proteins (those with an isoelectric point above pH 4), steps should be taken to remove excess salt

from the solution.

Thus the claims are rendered obvious.

[Applicants' priority claims of 5/22/98 and 5/27/97 are noted; however, document 97201607.5 has not been received, and no translation of WO 98/53702 has been provided. If document 97201607.5 is in French, and no translation is provided, the rejection over USP 5,968,586 will be maintained].

\*

Those references stricken from the IDS were so treated because of the absence of a translation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

PATENT EXAMINER GROUP 1300